



AUG 22 2000

Vernon Matheson
Operations Manager
Iceberg Industries Corporation
16 Forest Road, Suite 200
Post Office Box 8251, St. John's, NF
Canada, A1B 3N4

Re: Docket No.

Dear Mr. Matheson:

This is in response to your application to the Food and Drug Administration (FDA) for a temporary permit to market test, in interstate commerce, a product to be designated as "Borealis Iceberg Water" that will deviate from the U.S. standard of identity for bottled water (21 CFR 165.110) in that the source of the water is an iceberg and the name of the product is "Iceberg Water." In all other respects, the test product will conform to the standard for bottled water.

For the purposes of this permit, the name of the test product will be "Borealis Iceberg Water." The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9.

Relying on the representations made in your application, we are hereby granting your request to make interstate shipments for test marketing purposes of 150,000 cases of the 24 x 350 ml, 150,000 cases of the 12 x 1 L, and another 100,000 cases of the 24 x 500 ml giving 400,000 cases in total. The total fluid weight of the test product will be 1,124,024 gallons (4,260,000 liters). Finished labels must be submitted to the Director, Division of Standards and Labeling Regulations, HFS-820, Office of Nutritional Products, Labeling and Dietary Supplements, before the product is shipped in interstate commerce. The test product will be manufactured at Iceberg Industries Corporation Water Bottling Plant, located at Daniel's Point, Trepassey, Newfoundland, Canada, A0A 4B0. The product will be distributed by Iceberg Industries in the U.S. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101.

This permit will be effective for 15 months, beginning on the date the test product is introduced into interstate commerce, but not later than 90 days after notice of issuance of the permit is published in the Federal Register. You will notify FDA, in writing, of the date the 15-month period will begin, as soon as it is determined.

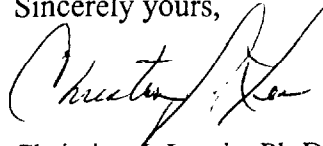
98P-0880

ANSI

Page 2 – Mr. Vernon Matheson

While this permit is in effect, FDA will refrain from recommending regulatory action against shipments of “Borealis Iceberg Water” covered by this permit on the grounds that the food fails to comply with 21 CFR 165.110.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Christine J. Lewis".

Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling,
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Page 3 – Mr. Vernon Matheson

cc:

GCF -1

HFA -224

HFA-305 (w/incoming)

HFS-1

HFS-4

HFS-22

HFS-800 (Lewis)

HFS-820 (Satchell)

HFS-822 (Carey)

HFS-636 (Wade)

R/D:HFS-822:LCarey:6/13/00: 202-205-4168:71141

Init:HFS-822:GJune:6/15/00

HFS-820:FSatchell:6/16/00

GCF-1:DDorsey:7/3/00

F/T:bls:7/12/00

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL
FOOD AND DRUG DIVISION
5600 FISHERS LANE
ROCKVILLE, MD 20857**

FACSIMILE TRANSMISSION RECORD

DATE: July 3, 2000

PAGES: 5 (including cover)

FROM: DAVID DORSEY

GCF-1, Room 5A-39

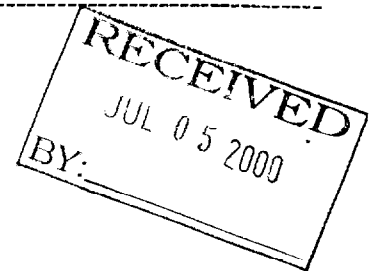
FAX: 301-827-7145

PHONE: 301-827-1142, 827-1131 (direct)

TO: LORETTA CAREY

FAX: 202-205-4594

PHONE: 202-205-5099



MESSAGE: Loretta, Comments on the iceberg water TMP. With these changes, I clear the documents. Please call if you have any questions. Thanks. David

NOTE: This transmission is from an NEC NEFAX 545 telecopier. If you do not receive a legible document, or do not receive all of the pages, please telephone me immediately at the voice number above.

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**ICEBERG
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CORPORATION**

June 6, 2000

Felicia B. Satchell
Chief, Food Standards Branch
Office of Food Labeling (HFS-158)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Re: 21 CFR 130.17 – Application for Temporary Marketing Permit for
Interests Shipment of Experimental Bottles of **Borealis Iceberg Water**.

Dear Ms. Satchell:

The name and address of the applicant is:

Iceberg Industries Corporation
16 Forest Rd., Suite 200
P.O. Box 8251, St. John's, NF
Canada, A1B 3N4

Iceberg Industries is regularly engaged in producing a variety of iceberg products, those being Borealis Iceberg Water, Borealis Iceberg Ice, Borealis Premium Vodka and Borealis Iceberg Beer.

The standard of identity for Beverages: Bottled Water; is prescribed in 21 CFR §165.110.

The proposed variation from the standard of identity is limited to our bottled water product being, Borealis, "Iceberg Water". Our water source is not provided for as a standard identity within the Code of Federal Regulations. Therefore, approval is requested for the addition of "Iceberg Water", to 21 CFR §165.110 as a standard identity so as to permit the use of this term on the label of the product.

The proposed new "Iceberg Water" product will be wholesome and non-deleterious. This product is a single ingredient product that is filtered several times and treated with ozone. The product is also subjected to appropriate analysis by certified laboratories, which is required by official government regulatory agencies, to ensure that it is safe and nutritious.

BOREALIS
ICEBERG
VODKA

BOREALIS
Canadian
Iceberg
WATER

DISCOVERY
Natural Spring Water



**ICEBERG
INDUSTRIES
CORPORATION**

The proposed variation from 21 CFR § 165.110, will result in the addition of "Iceberg water" as a Standard of Identity. No ingredient required by the standard of identity shall be eliminated, if such is the case with water.

The purpose of the variation is to sanction the use of Iceberg Water as the standard of identity on principal display panels of our labels. This statement is both truthful and precise, and can be verified with the documentation that has been enclosed for your information.

As stated in our previous application (Docket #98P0880) the proposed variation is of potential advantage to consumers as it would provide a clearly designated source of the water, as well as clarifying any confusion about the type of water it, in fact, is. The term "Bottled Water" which had first been recommended for our product can be concealing due to the broadness of the term, and most certainly, puzzling for the consumers who are trying to distinguish the differences between bottled waters. It neither informs the consumer of the source of the water, whereas "Iceberg Water" provides a clear and apparent explanation. It is also evident that this water should not be categorized as "Glacial Water" or "Glacial Fluvial", due to the information that can be found in documentation previously provided by Dr. Norman Catto, of Memorial University in St. John's NF.

According to his documentation, it is definitive that "Iceberg Water" has an even lower range of constituents than "Glacier water" which is derived from alpine glaciers that tend to collect minerals from contact surfaces of the mountains. The "Iceberg water" is also unique in character, due to the age, which is conceived by the scientific community to be as much as 100,000 years. Comparatively, the alpine glaciers are estimated to be 1000 years of age. This is also stated in Dr. Norman Catto's letter. Indeed, the "Iceberg Water" is genuinely distinctive from all other waters and, is recognized for it's unique characteristics by other countries, such as Canada.

I have enclosed the printer's proofs of the three labels that we will be using under this Temporary Marketing Permit. Since our last submission we have had to add a label to cover the proposed 500 ml bottle as well as changes to the labels to cover the addition of State permit numbers for New York and Connecticut and a refund declaration for the State of Maine. Actual labels will be forwarded upon request.

We are seeking a 15-month term for this Temporary Marketing Permit. During this time we will continue to develop and implement the marketing plan and strategies that were initiated under the previous permit. The term will also give us the opportunity to continue with the

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VODKA

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Contains
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detailed analysis of the growth and acceptance of the Iceberg Water in the USA markets.

Our marketing areas and initiatives have grown considerably during our previous Temporary Marketing Permit application. The projected distribution for this 15-month period is 150,000 cases of the 24 x 350 ml, 150,000 cases of the 12 x 1 L, and 100,000 cases of the 24 x 500ml totalling 400,000 cases.

The total fluid quantities as covered under this application will be 1,124,024 US gal. or the equivalent of 4,260,000 liters. This size shipment is necessary to cover our present and future marketing initiatives, plus ensure that we are able to manufacture the product within our budgetary constraints.

The areas of distribution are: All States of the United States of America

The "Borealis, Iceberg Water" product is manufactured at Iceberg Industries Corporation Water Bottling Plant, located at Daniel's Point, Trepassy, Newfoundland, Canada, A0A 4B0.

It is our intent to continue to distribute the product in the United States, as well as Canada, which is where it is manufactured.

Distribution through normal marketing channels, i.e. interstate distribution, is necessary so as to subject the Iceberg Water to the normal problems inherent with mass production, commercial viability, and public acceptance.

Sincerely,

Vernon Matheson – Operations Manager
Iceberg Industries Corporation

